



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,368	09/20/2004	Sven Morein	026220-00054	4091
4372	7590	11/21/2007	EXAMINER	
ARENT FOX LLP			AHMED, HASAN SYED	
1050 CONNECTICUT AVENUE, N.W.				
SUITE 400			ART UNIT	PAPER NUMBER
WASHINGTON, DC 20036			1615	
			NOTIFICATION DATE	DELIVERY MODE
			11/21/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DCIPDocket@arentfox.com
IPMatters@arentfox.com
Patent_Mail@arentfox.com

Office Action Summary	Application No.	Applicant(s)
	10/507,368	MOREIN ET AL.
	Examiner	Art Unit
	Hasan S. Ahmed	1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-42 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
 5) Claim(s) ____ is/are allowed.
 6) Claim(s) ____ is/are rejected.
 7) Claim(s) ____ is/are objected to.
 8) Claim(s) 1-42 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: ____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-9 and 19-25, drawn to a solid drug delivery composition comprising NO-donating NSAID(s) absorbed into porous particles.

Group II, claims 1, 10, and 12-18, drawn to a solid drug delivery composition comprising NO-donating NSAID(s) and surfactant(s) absorbed into porous particles.

Group III, claims 1 and 11, drawn to a solid drug delivery composition comprising a combination of NO-donating NSAID(s) with and without surfactant(s) absorbed into porous particles.

Group IV, claims 1, 26, and 27, drawn to a solid drug delivery composition comprising NO-donating NSAID(s) and surfactant(s) absorbed into porous particles mixed with enteric coated pellets comprising a H⁺, K⁺-ATPase inhibitor.

Group V, claims 1, 28, and 35-38, drawn to a process for producing porous particles comprising mixing the NO-donating NSAID(s) with porous particles.

Group VI, claims 1 and 29, drawn to a process for producing porous particles comprising dissolving the NO-donating NSAID(s) in alcohol.

Group VII, claims 1 and 30, drawn to a process for producing porous particles comprising melting the NO-donating NSAID(s).

Group VIII, claim 1 and 31, drawn to a process for producing porous particles comprising NO-donating NSAID(s) and surfactant(s) comprising mixing the NO-donating NSAID(s) and surfactant(s).

Group IX, claims 1 and 32, drawn to a process for producing porous particles comprising NO-donating NSAID(s) and surfactant(s) comprising melting the NO-donating NSAID(s) and surfactant(s).

Group X, claims 1, 33, and 34, drawn to a process for producing porous particles comprising NO-donating NSAIDS(s) comprising mixing the NO-donating NSAID(s) and the porous excipient.

Group XI, claims 1, 39, and 41, drawn to the use of a solid drug delivery composition for treating pain.

Group XII, claims 1, 40, and 42, drawn to the use of a solid drug delivery composition for treating inflammation.

* * * * *

The inventions listed as Groups I-XII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the common technical feature in all groups is a solid drug delivery composition comprising a NO-donating NSAID. WO 01/66088 ("Holmberg") teaches a solid drug delivery composition comprising a NO-donating NSAID (see abstract).

* * * * *

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Group I

Species I: form of NO-donating NSAID(s)

- oily (claim 2)
- melted (claim 3)

Species II: NO-donating NSAID(s)

- naproxen (claim 19)
- diclofenac (claim 21)
- ketoprofen (claim 24)

Species III: form of diclofenac

- diclofenac of claim 22
- diclofenac of claim 23

*

Group V

Species I: formulation

- tablet (claim 36)
- capsule (claim 37)

* * * * *

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Group I

Species I: form of NO-donating NSAID(s)

- oily (claim 2)
- melted (claim 3)

Species II: NO-donating NSAID(s)

- naproxen (claim 19)
- diclofenac (claim 21)
- ketoprofen (claim 24)

Species III: form of diclofenac

- diclofenac of claim 22
- diclofenac of claim 23

Group V

Species I: formulation

- tablet (claim 36)
- capsule (claim 37)

The following claim is generic: 1.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the various forms of NO-donating NSAID(s), NO-donating NSAID(s), forms of diclofenac, and formulations produce differing physiological effects.

* * * * *

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not

distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should Applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

★

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hasan S. Ahmed whose telephone number is 571-272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



HUMERA N. SHEIKH
PRIMARY EXAMINER